IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Karen L. FINCHER *et al.*		Art Unit:	1631
Appln. NO.:	09/732,627	Examiner:	CLOW, Lori A.
Filed:	12/08/2000	Atty. Docket:	16517.001/ 38-21(51770)B
For:	**Nucleic Acid Molecules**		

APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on January 29, 2003. The statutory fee of $320.00 for submitting this Brief should be charged to deposit account number 13-4125. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1, 10, and 11 are pending. Claims 2-9 were canceled. Appellant appeals all of the rejections of claims 1, 10, and 11.

4. Status of Amendments

Applicants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule reciting the sequence of an expressed sequence tag ("EST") and its complement. The nucleic acid molecule was derived from a cDNA collection prepared from *Gossypium hirsutum* male reproductive tissue (androecium). More particularly, the invention is directed to: a substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 (claim 1) and a substantially purified nucleic acid molecule comprising or consisting of a nucleic acid sequence of SEQ ID NO: 1 (claims 10 and 11).

6. Issues

The issues in this Appeal are:

(1) whether claims 1, 10, and 11 are unpatentable under 35 U.S.C. § 101 for alleged lack of patentable utility due to its not being supported by either a specific and/or substantial utility or a well established utility; and

(2) whether claims 1, 10, and 11 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility and one skilled in the art would not know how to use the claimed invention; and

(3) whether claims 1 and 10 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of written description due to its not conveying to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

7. Grouping of Claims

Patentability of claims 1, 10, and 11 is addressed together in Sections 8.A through 8.C below. Patentability of claims 1 and 10 is also addressed in Section 8.D below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the

public from an invention with substantial utility...where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have proven that the claimed nucleic acid molecule, in its current form, provides at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of a polymorphism in a population of corn plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecule provides at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101.

Applicants have shown that the claimed nucleic acid molecule actually works for that and other utilities disclosed and described in the specification, and so both enablement rejections must be reversed. Applicants have proven that one skilled in the art is able to use the claimed nucleic acid molecule for at least one disclosed utility, namely use as a genetic marker for genetic mapping. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Applicants have proven that the claimed nucleic acid molecule works for the disclosed utility, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acids that demonstrates Applicants' possession of the claimed invention. The genus of claimed nucleic acid molecules, *i.e.*, nucleic acid molecules "comprising" and "consisting of" SEQ ID NO. 1 have been described by the recitation of a "basic and novel" common structural feature – the nucleotide sequence of SEQ ID NO. 1 – which distinguishes them from nucleic acid molecules that are not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genus

of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1, 10, and 11 were erroneously rejected under 35 U.S.C. § 101, because the claimed invention was allegedly not supported by either "specific and/or substantial utility or a well established utility" as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Final Office Action dated October 31, 2002 (Paper No. 9) ("Final Action"). According to the Final Action, "the disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid." *See* Final Action at page 3.

The Examiner acknowledged that the specification describes the present invention as "useful as markers, the isolation of polypeptides, hybridization probes, primers the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping and numerous other generic genetic engineering usages, such as antisense production." *See* Final Action at page 3 and *See also* Office Action dated May 3, 2002 (Paper No. 6) at page 5. However, the Examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines because they are "non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acids being claimed." *See* Final Action at pages 3-4.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and ignores the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C.

§ 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown"). As acknowledged by the Examiner, the specification describes a utility, "a nucleic acid may be utilized to obtain a protein." *See* Final Action at page 4.

This use and others stated in the specification and by the Examiner are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequence possesses the requisite utility under 35 U.S.C. § 101.

The Examiner attempts to undermine the existing utilities by stating that the disclosed uses "are generic in nature and applicable to a myriad of such compounds." Final Action at page 4. In short, the Examiner's rejection, as it pertains to 35 U.S.C. § 101, rests on the premise that because other molecules might be used for the same purpose, the proposed utilities for the claimed molecules are legally insufficient. This position is wrong as a matter of law - there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206

U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178,199,17 U.S.P.Q. 154,162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicant notes that the claimed nucleic acid molecule encompasses many utilities. Furthermore, Applicant acquiesces that some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a unique subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicant asserts that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Furthermore, utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability - [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a

statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

In support of the position that the claimed nucleic acid molecules lack substantial utility, the Examiner states that "one skilled in the art would have reason to doubt that proposed sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence." *See* Final Action at page 5. The Examiner asserts, "Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research." *Id.*

Applicant disagrees and in the previous response referred the Examiner to the following articles, copies of which were provided to the Examiner, where sequence similarity is routinely used by those of ordinary skill in the art as a predictor of function. *See, e.g.*, Venter, *et al*, *The Sequence of the Human Genome*, Science, 291: 1304-1351 (2001); Woese, *et al*, *Conservation of Primary Structure in 16S RRNA*, Nature, 254: 83-85 (1975). Accordingly, Applicant maintains that one of ordinary skill in the art would have recognized, in light of Applicant's teachings, that at the time of filing Applicant had possession of the claimed invention for the uses described in the specification.

Furthermore, the utilities already described by the Examiner, *i.e.*, "useful as markers, the isolation of polypeptides, hybridization probes, primers the isolation of full- length cDNAs or genes", are not limited to a particular biological function. *See* Final Action at page 3. It is well known in the art that hybridization conditions affect the number of nucleic acid molecules isolated by any single nucleic acid probe. The limited pool of nucleic acid molecules or proteins recognized by SEQ ID NO: 1 are claimed based on sequence homology, not based on an admittedly unspecified biological function.

In view of the above, Applicant contends that the claimed nucleic acid molecules are supported by specific, substantial, and well established utilities disclosed in the specification. Moreover, the Examiner has failed to raise any relevant and credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1, 10, and 11 under 35 U.S.C. § 101 was improper and the rejection should be reversed.

C. The Claimed Nucleic Acids Are Enabled By The Specification

The enablement of the claimed nucleic acid molecule has been challenged. Claims 1, 10, and 11 were erroneously rejected as not enabled by the specification, because the claimed invention allegedly lacks utility and therefore cannot be enabled. *See* Final Action at page 9. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

The adequacy of the written description has been challenged by the Examiner because the nucleic acid molecules of claims 1 and 10 allegedly contain "...subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." *See* Final Action at page 9.

An adequate written description of a genus of nucleic acids, such as recited in claims 1 and 10, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents Of the University of California v. Eli Lilly and Co.,* 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.,* to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicant need not "describe", in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215,

211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicant to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (e.g., an open reading frame) be disclosed. *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner contends that "the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity of simplicity of the method of isolation". *See* Final Action at page 10. According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *See* Final Action at pages 10-11 and Office Action dated May 3, 2002 (Paper No. 6) at pages 9-10. Applicant respectfully disagrees. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 ("a CDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicant has provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable - they comprise a nucleic acid molecule having the sequence selected from the group consisting of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claims 1 and 10 and SEQ ID NO: 1. Thus, claims 1 and 10 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection must be withdrawn as improper.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: March 27, 2003

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APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.
2. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.
3. A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.